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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,858	08/20/2001	Friedrich Altmann		5615

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EXAMINER	
MCGARRY, SEAN	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,858	ALTMANN, FRIEDRICH	
	Examiner	Art Unit	
	Sean R. McGarry	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/30/04, 1/27/05*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-58 and 60-119* is/are pending in the application.

4a) Of the above claim(s) *35-48,53-56,64-75,78-82 and 85-107* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-52, 57, 58, 60-63, 76, 77, 83, 84, 108-119* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49-52, 57, 58, 60-63, 76, 77, 83, 84, and 108-119 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The specification discloses SEQ ID NO: 1, which corresponds to the cDNA encoding the mung bean species of α1, 3-fucosyl transferase. SEQ ID NO: 1 meets the written description provisions of 35 USC 112, first paragraph. However, the claims are directed to encompass methods that use, cells that contain and vectors that contain sequences that are and ribozymes that bind to and sequences that encode ribozymes that bind to; sequences that hybridize to SEQ ID NO: 1, corresponding sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a recited degree of identity (similarity, homology), and so forth. The claims embrace sequences from plants, insects and host cells in general. The range of species from which the sequence(s) is/are derived is unlimited. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. The

specification discloses only one example of a plant sequence (Mung bean) and provides no basis for what the structure of other plant α1, 3-fucosyl transferase sequences would be. It is stated, for example, at page 3, that the specificity of the enzyme from human cells is quite different than that of plant cells, for example. One in the art must rely on the broad range of potential and undescribed sequences to construct antisense/ribozyme expression vectors, cells containing such, vectors expressing ribozymes that may cleave undescribed mRNA. The claims embrace sequences that have 50% identity with SEQ ID NO: 1 and have a specified activity. No such sequences have beeen described other than SEQ ID NO: 1.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481,

1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* ,

984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only those embodiments drawn to SEQ ID NO: 1, but not the full breadth of the claims (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

The invention is drawn to vectors that contain a DNA of which is inversely orientated with respect to a promoter where the sequence is 50% homologous to SEQ ID NO: 1 or which hybridizes to SEQ ID NO: 1. The vector produces an antisense transcript of the DNA which antisense is intended to inhibit a GlcNAc-α1, 3-fucosyl transferase in cells that contain such a vector, a DNA molecule encoding a ribozyme targeting a plant α1, 3-fucosyl transferase nucleic acid as defined in claim claims 51 and 52) which inhibit a plant α1, 3-fucosyl transferase in cells (claims 62, 63, 76, 77, 83,and 84). The construction of the antisense and ribozyme expression vectors for use in the claimed invention require a description of the specific plant α1, 3-fucosyl transferase sequences targeted. At 50%, a ribozyme is not even required to target any sequence of SEQ ID NO: 1, but perhaps the other 50% that is not identical? How is this possibly described? As has been set forth above, only one such sequence, SEQ ID NO: 1, has been described in the instant specification. The instant specification does not provide any specific ribozyme sequences or antisense sequences other than those that are completely complimentary to a target nucleic acid sequence based on SEQ ID NO: 1, for example. The specification fails to provide any specific structure such that one in the art would know what structures would be required for the specific inhibition of any of a wide scope of plant α1, 3-fucosyl transferase nucleic acid targets embraced within the instant claims. No specific structure function relationship has been established in the specification or in the prior art for the antisense and ribozyme sequences for use in the instant invention, The specification also fails to provide an adequate description in figures or words since there is no disclosure of the structures of the target nucleic acids

let alone the structures of the antisense and ribozyme sequences instantly claimed, for example. The specification provides only trial and error methods that may find embodiments embraced within the scope of the claimed invention.

Applicant's arguments filed 9/30/2004 have been fully considered but they are not persuasive. Although the claims were not Officially rejected under 37 CFR 112 first paragraph in the previous Official Action applicant has addressed the reasons set forth in the action detailing how the claims would be potentially be rejected in this Official Action. Applicants arguments appear to be directed to the assertion that because there are methods outlined in the specification for finding embodiments within the scope of the claimed invention, there is adequate written description. It is the examiners position that this arguments is not convincing since as set forth in the rejection:

> Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Applicant asserts that the specification recites a hybridization stringency as well as a numerical figures with respect to the percent identity together with a functional enzyme activity. As was asserted in the rejection above, there has been no specific shared structure or sufficient numbers of species that would show a structure that provides the function disclosed an recited in the claims. One in the art, based on the specification simply, does not know the sequence, and hence structure, of the vast number of species contemplated in the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sean R McGarry
Primary Examiner
Art Unit 1635

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